NOTE:

The following pages are provided as a sample of the current Assistance Agreement Term and Conditions package. Some topics appear to have been repeated, however there are differences, which are explained with notes indicating when they are applicable. These determinations are the responsibility of the Grants Officer at USAMRAA and will be decided at the time of award.

U. S. ARMY MEDICAL RESEARCH ACQUISITION ACTIVITY

GENERAL TERMS AND CONDITIONS FOR ASSISTANCE AWARDS

TABLE OF CONTENTS

1. RECIPIENT RESPONSIBILITY (JAN 2000) (USAMRAA)

a. The recipient will bear primary responsibility for the conduct of the research and will exercise judgment towards attaining the stated research objectives within the limits of the award's terms and conditions.

b. The Principal Investigator(s) specified in the award document will be continuously responsible for the conduct of the research project and will be closely involved with the research effort. The Principal Investigator, operating within the policies of the recipient, is in the best position to determine the means by which the research may be conducted most effectively.

c. The recipient shall obtain the Grants Officer's prior approval to change the Principal Investigator, or to continue the research work during a continuous period of absence in excess of three (3) months, or a 25% reduction in time devoted to the project by the approved Principal Investigator.

d. The recipient shall obtain the Grants Officer's prior approval to change:

(1) the methodology or experiment when such is stated in the award as a specific objective;

(2) the stated objective of the research effort; or

(3) the phenomenon or phenomena under study.

2. ADMINISTRATION AND COST PRINCIPLES (JAN 2000) (USAMRAA)

The following Administrative and Cost Principles, as applicable, effective the earlier of (i) the start date of this award or (ii) the date on which the recipient incurs costs to be assessed the award, are incorporated as part of this award by reference:

a. OMB Circular A-21, "Cost Principles for Educational Institutions."

b. OMB Circular A-87, “Cost Principles for State, Local and Indian Tribal Governments."

c. OMB Circular A-102, “Grants and Cooperative Agreements with State and Local Governments.”

d. OMB Circular A-110, "Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-profit Organizations."

e. OMB Circular A-122, "Cost Principles for Non-profit Organizations." {For those nonprofit organizations specifically exempted from the provisions of OMB Circular A-122, Subpart 31.2 of the Federal Acquisition Regulations (FAR 48 CFR Subpart 31.2) shall apply}.

f. OMB Circular A-133, "Audits of States, Local Governments, and Non-Profit Organizations."

g. Federal Acquisition Regulation, Part 31.2 for Commercial Organizations.

h. Department of Defense Grant and Agreement Regulations 3210.6-R, Parts 32, 33 and 34.

These publications may be obtained from:

Office of Management and Budget
EOB Publications Office
New Executive Office Building
725 17th Street, NW, Room 2200
Washington DC 20503 Telephone: (202) 395-7332

These publications may be viewed at:

Website: www-usamraa.army.mil, then click reference library and select.

3. AWARD MODIFICATION (JAN 2000) (USAMRAA)

The only method by which this award may be modified is by a formal, written modification signed by the Grants Officer. No other communications, whether oral or in writing, are valid.

4. APPROVALS AND OTHER AUTHORIZATIONS (JAN 2000) (USAMRAA)

a. Prior approvals. All prior approvals required by OMB Circulars A-21, A-87, A-102, A-110, A-122, and A-133 are waived except the following:

(1) Change in the scope or objectives of the research project as required by paragraph 1 of these terms and conditions entitled "Recipient Responsibility."

(2) Any request for additional funding.

(3) Change in key personnel as required by paragraph 1 of these terms and conditions entitled "Recipient Responsibility."

(4) Exclusive of supplies, material, equipment or general support services, the award of a subaward to accomplish substantial programmatic work required in the agreement to be performed by the prime recipient.

(5) Unless identified in the budget incorporated as a part of the award, expenditures for individual items of general purpose equipment and specific purpose equipment costing $5,000 or more.

(6) Unless identified in the proposal, incorporated as part of the award, expenditure for foreign travel.

b. Preaward Costs. The recipient may incur preaward costs of up to 90 days prior to the start date of the award agreement. Preaward costs as incurred by the recipient must be necessary for the effective and economical conduct of the project, and the costs must be otherwise allowable in accordance with the appropriate cost principles. Preaward costs are made at the recipient's risk. The incurring of preaward costs by the recipient does not impose any obligation on the Government in the absence of appropriations, if an award is not subsequently made, or if an award is made for a lesser amount than the recipient expected.

c. Change in Performance Period. The recipient may make a one-time extension to the expiration date of the award for a period up to 12 months. The recipient shall notify the Grants Officer, in writing, at least 10 days prior to the expiration date of the award.

d. Unobligated Balances. In the absence of any specific notice to the contrary, the recipient is authorized to carry forward unexpended balances to subsequent funding periods of the award agreement.

5. GOVERNMENT INTERACTION (JAN 2000) (USAMRAA)

The active participants in this award are the U.S. Army Medical Research and Materiel Command (USAMRMC) and its laboratories identified herein through the U.S. Army Medical Research Acquisition Activity. The following USAMRMC Laboratory will be the focus of cooperative research conducted under this agreement:

5. RESERVED

6. PUBLICATION AND ACKNOWLEDGMENT (JAN 2000) (USAMRAA)

a. Publication. The recipient is encouraged to publish results of the research, unless classified, in appropriate journals. One copy of each paper planned for publication shall be submitted to the technical representative simultaneously with its submission for publication. Copies of all publications resulting from the research shall be forwarded to the Grants Officer as they become available, even though publication may in fact occur subsequent to the termination date of this award.

b. Acknowledgment. The recipient agrees that in the release of information relating to this award such release shall include statements to the effect that the project or effort depicted was sponsored by the Department of the Army and shall include:

(i) The Award Number;

(ii) "The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick MD 21702-5014 is the awarding and administering acquisition office." and;

(iii) A statement that the content of the information does not necessarily reflect the position or the policy of the Government, and no official endorsement should be inferred. For purposes of this article, information includes news releases, articles, manuscripts, brochures, advertisements, still and motion pictures, speeches, trade association proceedings, etc.

c. Prior to release to the public, the recipient shall notify the Grants Officer and the Grants Officer's Representative (GOR) of the following: planned news releases, planned publicity, advertising material concerning grant/cooperative agreement work, and planned presentations to scientific meetings. This provision is not intended to restrict dissemination of research information; the purpose is to inform the U.S. Army Medical Research and Materiel Command (USAMRMC) of planned public release of information on USAMRMC-funded research, in order to adequately respond to inquiries and to be alert to the possibility of inadvertent release of information which could be taken out of context.

7. TRAINING REPORTING REQUIREMENTS (JAN 2000) (USAMRAA)

Annual Summary

An original and two copies of a 2-5 page annual summary, presenting a description of the training and research accomplishments to date, shall be submitted within 30 calendar days after the anniversary date of the award to:

Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-RMI-S
504 Scott Street
Fort Detrick MD 21702-5012

No specific format for this summary is required, but the content should address the training and research accomplishments associated with the tasks outlined in the **approved** Statement of Work. Any technical or unexpected difficulties encountered and/or any deviations from the original Statement of Work should be addressed. Appended to this summary should be:

1) a bulleted list of **key** research accomplishments;

2) a list of **reportable outcomes** to include:

manuscripts, abstracts, presentations;
patents and licenses applied for and/or issued;
degrees obtained that are supported by this award;
development of cell lines, tissue or serum repositories;
informatics such as databases and animal models, etc.;
funding applied for based on work supported by this award;
employment or research opportunities applied for and/or received based on experiences/training supported by this award;

3) A copy of manuscripts or subsequent reprints resulting from the research shall be submitted to the USAMRMC. An extended abstract suitable for publication in the Proceedings of the Breast Cancer Research Program is required in relation to a DOD BCRP meeting planned during the term of this award. The extended abstract shall (1) identify the accomplishments since award and (2) follow instructions to be prepared by the USAMRMC and promulgated at a later date. The extended abstract style will be dependent on the discipline.

7. TECHNICAL REPORTING REQUIREMENTS (JAN 2000) (USAMRAA)

Format Requirements for Annual and Final Reports

a. Annual reports must provide a complete summary of the research accomplishments to date with respect to the **approved** Statement of Work. Journal articles **can be** substituted for detailed descriptions of the research, but the articles must be attached to the report as an appendix and appropriately referenced in the text. The importance of the annual report to decisions relating to continued support of the work effort cannot be overemphasized. An annual report shall be sent within 30 calendar days of the calendar anniversary date (only a final report will be required for last performance period or year) of the award.

b. A final report summarizing the entire intramural/extramural award effort, citing data in the annual reports and appended publications and providing a complete reporting of the research findings shall be submitted. Again, journal publications can be substituted for detailed descriptions of the research, but must be attached as an appendix and appropriately referenced in the text. The final report shall be sent at the end of the award performance period.

c. Although there is no page limitation for either the annual or final report, each report shall be of sufficient length to provide a comprehensive and thorough description of the accomplishments with respect to the **approved** Statement of Work. Submission of an original and two copies of the report are required. Reports shall be forwarded to:

Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-RMI-S
504 Scott Street
Fort Detrick MD 21702-5012

d. All annual and final reports shall have the following elements in this order: Front Cover, SF 298, Foreword, Table of Contents, Introduction, Body, Key Research Accomplishments, Reportable Outcomes, Conclusions, References, and Appendices. Pages shall be consecutively numbered throughout the report, including appendices. Mark all pages of the report which contain proprietary or unpublished data that should be protected. Indicate in your letter accompanying the report that the report contains proprietary or unpublished data, and that the distribution statement should indicate the limitations of the report.

FRONT COVER: A blank Front Cover will be provided by USAMRMC 60 days prior to the report due date. The Accession Document (AD) Number should remain blank. Indicate in a letter accompanying your report if the report contains proprietary data and that the distribution statement should be changed to limit the report to Government agencies only. Mark all pages in the report containing proprietary data.

STANDARD FORM (SF) 298, REPORT DOCUMENTATION PAGE: Use the partially completed SF 298 provided by USAMRMC 60 days prior to the report due date. Complete only Blocks 13, 14, and 15; all other fields should remain blank. The abstract in item 13 must state the purpose, scope, major findings and be an up-to-date report of the progress in terms of results and significance. Subject terms are the keywords previously assigned to your proposal abstract. RANK ORDER key words in item 14, with the most relevant first. The number of pages should include all pages that have printed data(including the front cover, SF298, Foreword, Table of Contents, and all Appendices). Please count pages carefully to ensure that there are no missing pages as this delays processing of reports. Page numbers should be typed: please do not hand number pages.

FOREWORD: Using the Foreword provided by USAMRMC 60 days prior to the report due date, initial **only** the statements that apply to the report. NOTE: Animals/Humans shall not be used in the research until all approvals have been received by your institute, and the animal/human statements shall not be initialed if the use of animals/humans has not been approved by this Command. Sign and date the Foreword page.

TABLE OF CONTENTS: Type on a separate page. When preparing the Table of Contents, please note the correct spelling of Foreword.

INTRODUCTION: Narrative that briefly (one paragraph) describes the subject, purpose, and scope of the research.

BODY: This section shall describe the research accomplishment associated with each Task outlined in the **approved** Statement of Work. Data presentation shall be comprehensive in providing a complete record of the research findings for the period of the annual/final report. However, appended publications and/or presentations **MAY** be substituted for a detailed description

but **MUST** be referenced in the BODY of the report. If applicable, for each Task outlined in the Statement of Work, reference appended publications and/or presentations for details of result findings and tables and/or figures. The report shall include negative as well as positive findings, and also shall include any problems in accomplishing any of the tasks. Statistical tests of significance shall be applied to all data whenever possible. Figures and graphs referenced in the text shall be appended. The discussion shall include the relevance to the original hypothesis. Recommended changes or future work to better address the research topic may also be included, although changes to the original statement of work must be approved by the Grants Officer.

KEY RESEARCH ACCOMPLISHMENTS: Bulleted list of **key** research accomplishments emanating from this research.

REPORTABLE OUTCOMES: Provide a list of reportable outcomes to include:

manuscripts, abstracts, presentations;
patents and licenses applied for and/or issued;
degrees obtained that are supported by this award;
development of cell lines, tissue or serum repositories;
informatics such as databases and animal models, etc.;
funding applied for based on work supported by this award;
employment or research opportunities applied for and/or received based on experiences/training supported by this award;

CONCLUSIONS: Summarize the results to include the importance and/or implications of the completed research and when necessary, recommend changes on future work to better address the problem. A "so what section" which evaluates the knowledge as a scientific or medical product shall also be included in the conclusion of the annual and final reports.

REFERENCES: List all references pertinent to the report using a standard journal format such as *Science, Military Medicine*, etc.

APPENDICES: Attach all appendices that contain information that supplements, clarifies or supports the text. Examples of appendices include journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

BINDING: Because all reports are entered into the Department of Defense Technical Reports Database collection and are microfiched, it is recommended that all reports be bound by stapling the pages together in the upper left hand corner. All reports shall be prepared in camera ready copy (legible print, clear photos/illustrations) for microfiching. Figures should include figure legends and all figures and tables should be clearly marked.

FINAL REPORTS: All final reports must include a bibliography of all publications and meeting abstracts and a list of personnel (not salaries) receiving pay from the research effort.

Manuscripts/Reprints, Abstracts

A copy of manuscripts or subsequent reprints resulting from the research shall be submitted to the USAMRMC. An extended abstract suitable for publication in the Proceedings of the Breast Cancer Research Program is required in relation to a DOD BCRP meeting planned during the term of this award. The extended abstract shall (1) identify the accomplishments since award and (2) follow instructions

to be prepared by the USAMRMC and promulgated at a later date. The extended abstract style will be dependent on the discipline.

8. FINANCIAL REPORTING REQUIREMENTS (JAN 2000) (USAMRAA)

The recipient shall submit on a quarterly basis a Standard Form 272, Federal Cash Transactions Report (Attachment 1). Each report shall be submitted to the U.S. Army Medical Research Acquisition Activity, ATTN: MCMR-AAA-_, 820 Chandler Street, Fort Detrick MD 21702-5014 in accordance with the following schedule:

Period Covered	Due Date
Jan - Mar	15 Apr
Apr - Jun	15 Jul
Jul - Sep	15 Oct
Oct - Dec	15 Jan

8. RESERVED

9. ADVANCE PAYMENTS AND INCREMENTAL FUNDING (JAN 2000) (USAMRAA)

a. Payments. Advance payments will be made to the recipient.

b. Electronic Funds Transfer. All advance payments to the recipient will be made by electronic funds transfer (EFT). The recipient shall contact the Defense Finance and Accounting System (DFAS) named on the face page of this award to make arrangements for EFT. Failure to do so may result in nonpayment.

c. Interest Bearing Account. The recipient shall deposit all advance payments in an interest bearing account. Interest over the amount of $250 per year shall be remitted annually to the Department of Health and Human Services, Payment Management System, P.O. Box 6021, Rockville, MD 20852. A copy of the transmittal letter stating the amount of interest remitted shall be sent to the U.S. Army Medical Research Acquisition Activity, ATTN: MCMR-AAA-__, 820 Chandler Street, Fort Detrick, MD 21702-5014.

d. It is estimated that the total cost to the Government for the full performance of this award shall be $_____. There have been funds allotted for payment of allowable costs incurred in the performance of this award in the amount of $_____. It is estimated that such funded amount shall be sufficient to cover allowable expenses until additional funds are provided for this award. Subject to the availability of funds, it is estimated that additional funds will be provided by modification in accordance with the following incremental schedule:

$	On or about 200_
$	On or about 200_
$	On or about 200_

e. Payments under this award will be made to the recipient in accordance with the schedule outlined below. If the recipient fails to perform, the Grants Officer shall notify DFAS in writing to withhold payments.

f. Advance Payment Schedule:

Year One $_____

Amount	On or About

$_____	Upon execution of this award
$_____	(Enter DAY/MONTH/YEAR)
$_____	(Enter DAY/MONTH/YEAR)
$_____	(Enter DAY/MONTH/YEAR)

Year Two $_____

Amount	On or About
$_____	(Enter DAY/MONTH/YEAR)
$_____	(Enter DAY/MONTH/YEAR)
$_____	(Enter DAY/MONTH/YEAR)
$_____	(Enter DAY/MONTH/YEAR)

Year Three $_____

Amount	On or About
$_____	(Enter DAY/MONTH/YEAR)
$_____	(Enter DAY/MONTH/YEAR)
$_____	(Enter DAY/MONTH/YEAR)
$_____	(Enter DAY/MONTH/YEAR)

Year Four $_____

Amount	On or About
$_____	(Enter DAY/MONTH/YEAR)
$_____	(Enter DAY/MONTH/YEAR)
$_____	(Enter DAY/MONTH/YEAR)
$_____	(Enter DAY/MONTH/YEAR)

9. ADVANCE PAYMENTS AND FULL FUNDING (JAN 2000) (USAMRAA)

a. Payments. Advance payments will be made to the recipient.

b. Electronic Funds Transfer. All advance payments to the recipient will be made by electronic funds transfer (EFT). The recipient shall contact the Defense Finance and Accounting System (DFAS) named on the face page of this award to make arrangements for EFT. Failure to do so may result in nonpayment.

c. Interest Bearing Account. The recipient shall deposit all advance payments in an interest bearing account. Interest over the amount of $250 per year shall be remitted annually to the Department of Health and Human Services, Payment Management System, P.O. Box 6021, Rockville, MD 20852. A copy of the transmittal letter stating the amount of interest remitted shall be sent to the U.S. Army Medical Research Acquisition Activity, ATTN: MCMR-AAA-__, 820 Chandler Street, Fort Detrick, MD 21702-5014.

d. If the recipient fails to perform, the Grants Officer shall notify DFAS in writing to withhold payments.

e. Advance Payment Schedule.

Year One $_____

Amount	On or About
$_____	Upon execution of this award
$_____	(Enter DAY/MONTH/YEAR)
$_____	(Enter DAY/MONTH/YEAR)
$_____	(Enter DAY/MONTH/YEAR)

Year Two $_____

Amount	On or About
$_____	(Enter DAY/MONTH/YEAR)
$_____	(Enter DAY/MONTH/YEAR)
$_____	(Enter DAY/MONTH/YEAR)
$_____	(Enter DAY/MONTH/YEAR)

Year Three $_____

Amount	On or About
$_____	(Enter DAY/MONTH/YEAR)
$_____	(Enter DAY/MONTH/YEAR)
$_____	(Enter DAY/MONTH/YEAR)
$_____	(Enter DAY/MONTH/YEAR)

Year Four $_____

Amount	On or About
$_____	(Enter DAY/MONTH/YEAR)
$_____	(Enter DAY/MONTH/YEAR)
$_____	(Enter DAY/MONTH/YEAR)
$_____	(Enter DAY/MONTH/YEAR)

9. COST REIMBURSEMENT PAYMENTS AND INCREMENTAL FUNDING (JAN 2000) (USAMRAA)

a. Payments. Payments under this award shall be made to the recipient on a cost reimbursement basis. The recipient shall submit one original Standard Form 270, Request for Advance or Reimbursement (Attachment 1), monthly, but not less frequently than quarterly, to:

U.S. Army Medical Research Acquisition Activity
ATTN: MCMR-AAA-___
820 Chandler Street
Fort Detrick MD 21702-5014

No payment will be made if the recipient fails to submit the required form. Failure to invoice at least quarterly may result in delay of payment and may be cause for termination of the grant.

b. Electronic Funds Transfer. All payments to the recipient will be made by electronic funds transfer (EFT). The recipient shall contact the Defense Finance and Accounting System (DFAS) named on the face page of this award to make arrangements for EFT. Failure to do so may result in nonpayment.

c. It is estimated that the total cost to the Government for the full performance of this award shall be $_____. There have been funds allotted for payment of allowable costs incurred in the performance of this award in the amount of $_____. It is estimated that such funded amount shall be sufficient to cover allowable expenses until additional funds are provided for this award. Subject to the availability of funds, it is estimated that additional funds will be provided by modification in accordance with the following incremental schedule:

$	On or about 200_
$	On or about 200_
$	On or about 200_

9. COST REIMBURSEMENT PAYMENTS AND FULL FUNDING (JAN 2000) (USAMRAA)

a. Payments. Payments under this award shall be made to the recipient on a cost reimbursement basis. The recipient shall submit one original Standard Form 270, Request for Advance or Reimbursement (Attachment 1), monthly, but not less frequently than quarterly, to:

U.S. Army Medical Research Acquisition Activity
ATTN: MCMR-AAA-___
820 Chandler Street
Fort Detrick MD 21702-5014

No payment will be made if the recipient fails to submit the required form. Failure to invoice at least quarterly may result in delay of payment and may be cause for termination of the grant.

b. Electronic Funds Transfer. All payments to the recipient will be made by electronic funds transfer (EFT). The recipient shall contact the Defense Finance and Accounting System (DFAS) named on the face page of this award to make arrangements for EFT. Failure to do so may result in nonpayment.

10. SUSPENSION AND TERMINATION (JAN 2000) (USAMRAA)

a. The Grants Officer may terminate or suspend in whole or in part, this agreement by written notice to the recipient upon a finding that the recipient has failed to comply with the material provisions of this agreement, if the recipient materially changes the objective of the agreement, or if appropriated funds are not available to support the program. However, the Grants Officer may immediately suspend or terminate the award without prior notice when such action is necessary to protect the interests of the Government.

b. Additionally, this agreement may be terminated by either party upon written notice to the other party, based upon a reasonable determination that the project will not produce beneficial results commensurate with the expenditure of resources. Such written notice shall be preceded by consultation between the parties. In the event of a termination, the Government shall have a paid-up license in any subject invention, copyright work, data or technical data made or developed under this agreement.

c. No costs incurred during a suspension period or after the effective date of a termination will be allowable, except those costs which, in the opinion of the Grants Officer, the recipient could not reasonably avoid or eliminate, or which were otherwise authorized by the suspension or termination notice, provided such costs would otherwise be allowable under the terms of the

award and the applicable Federal cost principles. In no event will the total of payments under a terminated award exceed the amount obligated in this award.

11. AWARD CLOSE OUT WITH ADVANCE PAYMENTS (FEB 2000) (USAMRAA)

a. The recipient shall submit an original SF 272, Federal Cash Transactions Report (Attachment 1) within 30 calendar days following the end of the final quarter.

b. The following documents shall be submitted within 30 days following the research ending date:

(1) Final Scientific Report, as listed in Paragraph 7.

(2) Patent Report (DD Form 882, Report of Inventions and Subcontracts) (Attachment 2); submit as specified in Paragraph 16.

(3) Cumulative listing of only the nonexpendable personal property acquired with award funds **for which title has not been vested to your institution**. (This may be submitted on your institution's letterhead.)

(4) Volunteer Registry Data Sheet, USAMRDC Form 60-R (Attachment _). The Principal Investigator shall be directed to complete a form for each subject enrolled in this study and forwarded in accordance with the clause entitled "Use of Human Subjects."

c. In the event a final audit has not been performed prior to the closeout of the award, the sponsoring agency will retain the right to recover an appropriate amount after fully considering the recommendations on disallowed costs resulting from the final audit.

11. AWARD CLOSE OUT WITH COST REIMBURSEMENT PAYMENTS (FEB 2000) (USAMRAA)

a. The recipient shall submit a final SF 270, Request for Advance o r Reimbursement (Attachment 1), within 30 calendar days following the end of the final quarter.

b. The following documents shall be submitted within 30 days following the research ending date:

(1) Final Scientific Report, as listed in Paragraph 7.

(2) Patent Report (DD Form 882, Report of Inventions and Subcontracts) (Attachment 2); submit as specified in Paragraph 16.

(3) Cumulative listing of only the nonexpendable personal property acquired with award funds **for which title has not been vested to your institution**. (This may be submitted on your institution's letterhead.)

(4) Volunteer Registry Data Sheet, USAMRDC Form 60-R (Attachment _). The Principal Investigator shall be directed to complete a form for each subject enrolled in this study and forwarded in accordance with the clause entitled "Use of Human Subjects."

c. In the event a final audit has not been performed prior to the closeout of the award, the sponsoring agency will retain the right to recover an appropriate amount after fully considering the recommendations on disallowed costs resulting from the final audit.

12. SITE VISITS (JAN 2000) (USAMRAA)

The Grants Officer, through authorized representatives, has the right at all reasonable times to make site visits to review project accomplishments and to provide such technical assistance as may be required. If any site visit is made by the Government representative on the premises of the recipient or subrecipient, the recipient shall provide, and shall require its subrecipients to provide, all reasonable facilities and assistance for the safety and convenience of the Government representatives in the performance of their duties. All site visits and evaluation shall be performed in such a manner as will not unduly interfere with or delay the work.

13. TITLE TO PROPERTY ACQUIRED WITH FEDERAL FUNDS (EDUCATIONAL AND NON-PROFIT)(JAN 2000) (USAMRAA)

a. Unless otherwise specified in the Award Schedule, title to all items of tangible personal property acquired with Federal funds under this award shall vest in the recipient upon acquisition without further obligation to the Federal Government.

b. Real property acquired in whole or in part with Federal funds shall be governed by the DOD Grant and Agreement Regulations 3210.6-R, Paragraph 32.32.

13. TITLE TO REAL PROPERTY AND EQUIPMENT (FOR-PROFIT)(JAN 2000) (USAMRAA)

Real property and equipment acquired in whole or in part with Federal funds shall be governed by the DOD Grant and Agreement Regulations 3210.6-R, Paragraph 34.21.

14. FEDERALLY OWNED PROPERTY (EDUCATIONAL AND NON-PROFIT) (JAN 2000) (USAMRAA)

Title to Federally owned property remains vested in the Federal Government, and is subject to the requirements of the DOD Grant and Agreement Regulations 3210.6-R, Paragraph 32.33.

14. FEDERALLY OWNED PROPERTY (FOR-PROFIT) (JAN 2000) (USAMRAA)

Title to Federally owned property remains vested in the Federal Government, and is subject to the requirements of the DOD Grant and Agreement Regulations 3210.6-R, Paragraph 34.22.

15. INTANGIBLE PROPERTY (EDUCATIONAL AND NON-PROFIT)(JAN 2000) (USAMRAA)

Rights in technical data, patents, inventions, and computer software under this award shall be as specified in the DOD Grant and Agreement Regulations 3210.6-R, Paragraph 32.36.

15. INTELLECTUAL PROPERTY (FOR-PROFIT)(JAN 2000) (USAMRAA)

Rights in technical data, patents, inventions, and computer software under this award shall be as specified in the DOD Grant and Agreement Regulations 3210.6-R, Paragraph 34.25.

16. PATENTS AND INVENTIONS (JAN 2000) (USAMRAA)

a. The recipient shall use the Interagency Edison through the National Institutes of Health Commons (http://www.iedison.gov) for filing of Patent Application and Invention Disclosure. Negative reports are required and shall be submitted on a DD Form 882 to the Grants Officer.

b. Invention reports are due annually and at the end of the period of the award. Annual reports are due 30 days after the anniversary date of the award and final reports are due 30 days after the expiration of the award. The award will NOT be closed out until all invention reporting requirements are met.

17. DISPUTES (JAN 2000) (USAMRAA)

Disagreements regarding issues concerning assistance agreements between the recipient and the Grants Officer shall, to the maximum extent possible, be resolved by negotiation and mutual agreement at the Grants Officer level. If agreement cannot be reached, it is our policy to use alternative dispute resolution (ADR) procedures that may either be agreed upon by the Government and the recipient in advance of the award or may be agreed upon at the time the parties determine to use ADR procedures. If the parties cannot agree on the use of ADR procedures, the recipient can submit, in writing, a disputed claim or issue to the Grants Officer. The Grants Officer will consider the claim or disputed issue and prepare a written decision within 60 days of receipt. The Grants Officer's decision will be final. The recipient may appeal the decision within 90 days after receipt of such notification. Appeals will be resolved by the Head of the Contracting Activity. The decision by the Head of the Contracting Activity will be final and not subject to further administrative appeal. However, the recipient does not waive any legal remedy, such as formal claims, under Title 28 United State Code 1492, by agreeing to this provision.

18. USE OF HUMAN SUBJECTS (JAN 2000) (USAMRAA)

a. The recipient or its subrecipients, are authorized to conduct research under this award involving humans as research subjects for the following protocols:

Protocols not identified are not approved.

b. Recipients and subrecipients are required to submit documentation of IRB review of protocols and consent forms from each of the funded institutions. Research at funded institutions may not begin until the U.S. Army Surgeon General’s Human Subjects Research Review Board approves the protocol and consent form for that site.

c. Recipients and subrecipients who enroll additional unfunded institutions are responsible to ensure that the institute conducts research in accordance

with 45 CFR 46 and other applicable federal and state regulations. Prior to inclusion of any unfunded institution's participation under this award, the recipient is responsible to notify the Grants Officer.

d. Volunteer Registry Data Sheet (USAMRDC Form 60-R). In accordance with the "Use of Human Subjects" provision above, the Volunteer Registry Data Sheet, USAMRDC Form 60-R (Attachment _), is to be completed at the time the subject consents to participate and is entered into the study. The form shall be submitted to the Commander, U.S. Army Medical Research and Materiel Command, ATTN: MCMR-RCQ-HR, 504 Scott Street, Fort Detrick, MD 21702-5012 upon completion of the research project or upon expiration/termination of the award, whichever occurs first.

18. PROHIBITION OF USE OF HUMAN SUBJECTS (JAN 2000) (USAMRAA)

Notwithstanding any other provisions contained in this award or incorporated by reference herein, the recipient is expressly forbidden to use or subcontract for the use of human subjects in any manner whatsoever. In the performance of this award, the recipient agrees not to come into contact with, use or employ, or subcontract for the use or employ of any human subjects for research, experimentation, tests or other treatment under the scope of work as set out in the award

19. USE OF HUMAN ANATOMICAL SUBSTANCES (JAN 2000) (USAMRAA)

a. The recipient,or its subrecipients, are authorized to c onduct research under this award involving human anatomical substances for the following protocols:

Protocols not identified are not approved.

b. Any anatomical substance (organs, tissues, or tissue fluids) linked by identifiers to a particular person and used for research under this award shall be donated for the purpose of research or investigation. The donor shall be the person from whom the substance is removed or, in the event of death or legal disability of the person from whom the substance is removed, the next of kin or legal representative of such person. Donation shall be made by written consent and shall relinquish all ownership and/or rights to the substance. All human anatomical substances used in research under this award shall be lawfully acquired. It should be noted that a general autopsy consent form or a consent to perform surgery, in and of themselves, may not be adequate. If excised or autopsy tissue is to be used, the protocol shall include a copy of the consent form used to obtain the tissue.

19. PROHIBITION OF USE OF HUMAN ANATOMICAL SUBSTANCES (JAN 2000) (USAMRAA)

Notwithstanding any other provisions contained in this award or incorporated by reference herein, the recipient is expressly forbidden to use or subcontract for the use of human anatomical substances in any manner whatsoever. In the performance of this award, the recipient agrees not to come into contact with, use or employ, or subcontract for the use or employ of any human anatomical substances for research, experimentation, tests or other treatment under the scope of work as set out in the award.

20. USE OF LABORATORY ANIMALS (CONUS)(JAN 2000) (USAMRAA)

a. ANIMAL WELFARE

(1) The recipient shall register its research facility with the Secretary of Agriculture in accordance with 7 U.S.C. 2316 and 9 CFR, Subchapter A, Part 2, Subpart C, and Section 2.30, and furnish evidence of such registration to the Grants Officer before beginning work under this award.

(2) The recipient shall acquire animals only from dealers licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR, Subchapter A, Part 2, Subpart A, Sections 2.1 through 2.11, or from sources that are exempt from licensing under those sections.

(3) The recipient agrees that the care and use of animals will conform with the pertinent laws of the United States and regulations of the Department of Agriculture (see 7 U.S.C. 2131 *et.seq.* and 9 CFR Subchapter A, Parts 1 through 4).

(4) The Grants Officer may immediately suspend, in whole or in part, work and further payments under this award for failure to comply with the requirements of paragraphs (a) through (c) of this clause.

(a) The suspension will stay in effect until the recipient complies with the requirements.

(b) Failure to complete corrective action within the time specified by the Grants Officer may result in termination of this award and removal of the recipient's name from the list of contractors with approved Public Health Service Welfare Assurances.

(5) The recipient may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA), for the region in which its research facility is located. The location of the appropriate APHIS regional office, as well as information concerning this program may be obtained by contacting the Senior Staff Officer, Animal Care Staff, USDA/APHIS, Animal Care, 4700 River Road, Unit 84, Riverdale, MD 20737-1234 (Phone number 301-734-7833).

(6) The recipient shall include this clause, including this paragraph (6), in all subcontracts/subawards involving research of live vertebrate animals.

b. POST-AWARD OVERSIGHT OF THE USE OF LABORATORY ANIMALS

Award post-award oversight of the use of laboratory animals shall be the responsibility of the recipient's Animal Care and Use Committee (ACUC). The Principal Investigator will notify the Grants Officer in writing of any significant changes to the proposed use of animals which was the basis for award. These changes must be approved by the recipient's ACUC and the USAMRMC. In addition, the ACUC shall immediately notify the Grants Officer of any violations of law, regulation, or publication cited above.

c. ANIMAL USE REPORTING

(1) The recipient shall prepare and submit annually the U.S. Army Medical Research and Materiel Command Animal Use Report (Attachment _) detailing the use of animals in the research and development sponsored by the Army. The

reporting period shall be each Federal Fiscal Year, i.e., 1 October through 30 September, each year. Additionally, the recipient shall furnish a copy of the most recent USDA Inspection Report (APHIS Form 7008 and Continuation Sheets APHIS Form(s) 7100). The recipient is responsible for ensuring that a separate U.S. Army Medical Research and Materiel Command Animal Use Report and USDA Inspection Report (APHIS Form 7008 and Continuation Sheets APHIS Form(s) 7100) be submitted for any subcontract/subaward facility using animals.

(2) The following definitions shall apply to the U.S. Army Medical Research and Materiel Command Animal Use Report:

(a) Column A. Animal. List all animal types by common name used for the particular work unit or protocol. For the purposes of this reporting requirement, an animal is defined as any live nonhuman vertebrate, used for research, development, test, and evaluation (RDT&E), clinical investigations, diagnostic procedures, and/or instructional programs. Only animals that are on hand in the facility or acquired during the reporting fiscal year should be reported. Animal organs, tissues, cells, fluid components, and/or by-products purchased or acquired as such animal/biological components should not be reported.

(b) Column B. Number of animals purchased, bred or housed but not yet used. The term **"animals purchased or bred"** refers to the purchase, breeding, or other acquisition of individual animals in the reporting fiscal year for assignment to a particular work unit or protocol. Animals carried over from the previous fiscal year and not yet used in any procedures or studies **must be** included in this number for the work unit or protocol to which they are assigned.

(c) Columns C-F. Number of animals used. A single animal must be counted only once in determining the number of animals used during the fiscal year for a particular work unit or protocol. The term **"animals used" does not** refer to the number of times an individual animal is injected, manipulated, handled, or administered medication and/or experimental compounds within a given work unit, protocol, or program. Animals on hand during the reporting fiscal year, but not actually used during the fiscal year **must not** be included in this column.

(i) Column C. Number of animals used involving no pain or distress. The number of animals placed in this column must have been used in procedures which did not cause more than slight or momentary pain or distress, as defined by the institution's ACUC and 9 CFR, Subchapter A, Part 1.

(ii) Column D. Number of animals used in which appropriate anesthetic, analgesic, or tranquilizing drugs were used to alleviate pain. The number of animals placed in this column must have received appropriate pharmacological agents to relieve pain or distress, as defined by the institution's ACUC and 9 CFR, Subchapter A, Part 1.

(iii) Column E. Number of animals used in which pain or distress was not alleviated. Animals counted in this column were not given pharmacological agents to relieve pain or distress, as defined by the institution's ACUC and 9CFR, Subchapter A, Part 1.

(iv) Column F. Total Number of Animals Used.

(3) Animal Use Report

(a) The recipient shall submit the U.S. Army Medical Research and Materiel Command Animal Use Report and a copy of the most recent USDA Inspection Report (APHIS Form 7008 and Continuation Sheets APHIS Form(s) 7100) each year, no later than 1 December.

(b) These reports shall be submitted to:

Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-RCQ-AR
504 Scott Street
Fort Detrick MD 21702-5012

20. USE OF LABORATORY ANIMALS (OCONUS)(JAN 2000) (USAMRAA)

a. USE OF LABORATORY ANIMALS (OCONUS)

All laws, customs, and practices of the country in which the research is to be conducted shall be complied with insofar as use of laboratory animals is concerned. In those instances where the local laws and regulations are in conflict with the laws and regulations of the United States and the Department of Agriculture, the more humane and stringent will be followed. The following U.S. standards and regulations for the protection, treatment, and use of animals should be adhered to where practicable: 7 U.S. Code 2131 et. seq. and 9 Code of Federal Regulations, Subchapter A, Parts 1 - 4.

b. POST-AWARD OVERSIGHT OF THE USE OF LABORATORY ANIMALS

Award post-award oversight of the use of laboratory animals shall be the responsibility of the recipient's Animal Care and Use Committee (ACUC). The Principal Investigator will notify the Grants Officer in writing of any significant changes to the proposed use of animals which was the basis for award. These changes must be approved by the recipient's ACUC and the USAMRMC. In addition, the ACUC shall immediately notify the Grants Officer of any violations of law, regulation, or publication cited above.

c. ANIMAL USE REPORTING

(1) The recipient shall prepare and submit annually the U.S. Army Medical Research and Materiel Command Animal Use Report (Attachment _) detailing the use of animals in the research and development sponsored by the Army. The reporting period shall be each Federal Fiscal Year, i.e., 1 October through 30 September, each year. The recipient is responsible for ensuring that a separate U.S. Army Medical Research and Materiel Command Animal Use Report is submitted for any subcontract/subaward facility using animals.

(2) The following definitions shall apply to the U.S. Army Medical Research and Materiel Command Animal Use Report:

(a) Column A. Animal. List all animal types by common name used for the particular work unit or protocol. For the purposes of this reporting requirement, an animal is defined as any live nonhuman vertebrate, used for research, development, test, and evaluation (RDT&E), clinical investigations, diagnostic procedures, and/or instructional programs. Only animals that are on hand in the facility or acquired during the reporting fiscal year should be reported. Animal organs, tissues, cells, fluid components, and/or by-products purchased or acquired as such animal/biological components should not be reported.

(b) Column B. Number of animals purchased, bred or housed but not yet used. The term **"animals purchased or bred"** refers to the purchase, breeding, or other acquisition of individual animals in the reporting fiscal year for assignment to a particular work unit or protocol. Animals carried over from the previous fiscal year and not yet used in any procedures or studies **must be** included in this number for the work unit or protocol to which they are assigned.

(c) Columns C-F. Number of animals used. A single animal must be counted only once in determining the number of animals used during the fiscal year for a particular work unit or protocol. The term **"animals used" does not** refer to the number of times an individual animal is injected, manipulated, handled, or administered medication and/or experimental compounds within a given work unit, protocol, or program. Animals on hand during the reporting fiscal year, but not actually used during the fiscal year **must not** be included in this column.

(i) Column C. Number of animals used involving no pain or distress. The number of animals placed in this column must have been used in procedures which did not cause more than slight or momentary pain or distress, as defined by the institution's ACUC and 9 CFR, Subchapter A, Part 1.

(ii) Column D. Number of animals used in which appropriate anesthetic, analgesic, or tranquilizing drugs were used to alleviate pain. The number of animals placed in this column must have received appropriate pharmacological agents to relieve pain or distress, as defined by the institution's ACUC and 9 CFR, Subchapter A, Part 1.

(iii) Column E. Number of animals used in which pain or distress was not alleviated. Animals counted in this column were not given pharmacological agents to relieve pain or distress, as defined by the institution's ACUC and 9CFR, Subchapter A, Part 1.

(iv) Column F. Total Number of Animals Used.

(3) Animal Use Report

(a) The recipient shall submit the U.S. Army Medical Research and Materiel Command Animal Use Report each year, no later than 1 December.

(b) These reports shall be submitted to:

Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-RCQ-AR
504 Scott Street
Fort Detrick MD 21702-5012

20. PROHIBITION OF USE OF LABORATORY ANIMALS (JAN 2000) (USAMRAA)

Notwithstanding any other provisions contained in this award or incorporated by reference herein, the recipient is expressly forbidden to use or subcontract for the use of laboratory animals in any manner whatsoever without the express written approval of the Grants Officer.

21. YEAR 2000 COMPLIANCE (JAN 2000) (USAMRAA)

The recipient shall make every reasonable effort to ensure that all hardware, software, firmware, and middleware (whether acting alone or combined as a system), utilized in this award shall be Year 2000 compliant.

22. ATTACHMENTS

ATTACHMENT 1 - SF 272, Federal Cash Transactions Report
ATTACHMENT 1 - SF 270, Request for Advance or Reimbursement
ATTACHMENT 2 - DD Form 882, Report of Inventions and Subcontracts
ATTACHMENT - USAMRDC Form 60-R, Volunteer Registry Data Sheet
ATTACHMENT - U.S. Army Medical Research and Materiel Command Animal Use Report